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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/306,662	05/05/1999	MARK K. MALMROS	PRO-SE	3760

7590 11/26/2001

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RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
1642	18

DATE MAILED: 11/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/306,662	Applicant(s) MALMROS ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7-13 and 17-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7-13 and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,5,7-13 and 17-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Detailed Action

1. The request filed on September 13, 2001 in Paper No. 15 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/306,662 is acceptable and a CPA has been established. An action on the CPA follows.

2. The amendment filed on September 13, 2001 in Paper No. 14 is acknowledged and has been entered. Claims 2, 4, 6, 14, and 16 have been canceled. Claims 1, 3, 5, 7, 9-13, 15, and 17-19 have been amended.

3. The amendment filed on October 15, 2001 in Paper No. 17 is acknowledged and has been entered. Claims 3 and 15 have been canceled. Claims 1, 12, and 13 have been amended.

4. Claims 1, 5, 7-13, and 17-19 are pending in the application and are currently under prosecution.

Election/Restrictions

5. The Election without traverse in response to the Office Action mailed September 29, 2000 (Paper No. 3) is acknowledged and has been entered. Applicant elects the claims drawn to the species comprising skin.

Specification

6. The specification is objected to because of the following informalities:

The terms "metaplasic" and "dysplasic" appear to be misspellings of the terms "metaplastic" and "dysplastic". Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 5, 7-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for making an *in situ* diagnosis or analysis of biological tissue and cells of living organisms.

The specification teaches that "the use of biological stains in direct staining *in vivo* has been shown to have a high degree of sensitivity to a variety of metaplasic, pre-cancerous, and cancerous cells and tissues" (page 20, lines 3-5). The specification teaches general methods of applying reflectance spectroscopy to diagnose and/or treat diseased tissue and/or cells (pages 20-23), comprising the direct application of a stain to living tissue, wherein the properties and characteristics of the stain is controlled (page 20, lines 19-22) and further comprising irradiation of the stained tissue, collection and measurement of reflected light (page 20, line 29 to page 21, line 4), and analysis of the data by software means using a microcomputer (page 21, lines 4-8).

One cannot extrapolate the teachings of the specification to the enablement of the invention commensurate in scope with the claims because there is insufficient guidance and exemplification to enable one skilled in the art to practice the claimed invention with a reasonable expectation of success without first having to perform extensive and undue experimentation.

Factors to be considered in determining whether undue experimentation is required are summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the

breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The specification teaches, "the specificity of the staining process in differentiating between the stage and type of metaplasia has been variable and has **not** allowed for a definitive diagnosis of the disease state" (emphasis added) (page 20, lines 8-10). Further, the specification teaches, "vital or *in vivo* staining has **not** been able to distinguish between normal cellular repair processes and metaplasia" (emphasis added) (page 20, lines 10-11). However, the specification does not provide sufficient guidance with regard to these issues; nor does it propose or explain the rationale by which these shortcomings or misconceptions are rendered solved by the claimed invention or to be considered inaccurate. Moreover, the specification does not teach that the method can be applied to any particular tissue type or cell type, and to which, if any, of these tissues and cells the method cannot be applied. The specification provides no working examples that would provide guidance to one skilled in the art to use the invention. Accordingly, no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed method or to use the invention, commensurate in scope with the claims, with a reasonable expectation of success.

In addition, certainly the guidance or exemplification that is provided in the specification is not reasonably commensurate in scope with the claims. For example, the specification does not teach the use of all the thiazine dyes, but each dye would be expected to have different staining properties. Also, the specification does not teach the use of the claimed method to diagnose any disease state. In view of the high level of unpredictability in the art, one skill in the art would not accept the assertion that the method can be used to the breadth of the scope of the claims with a reasonable expectation of success based only upon the instant disclosure.

In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

9. Claims 13 and 17-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the cytotoxic destruction of

dysplastic, pre-cancerous, or cancerous cells *of the skin*, does not reasonably provide enablement for a method of cytotoxic destruction of dysplastic, pre-cancerous, or cancerous cells *in any tissue*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to a method for the cytotoxic destruction of dysplasic, pre-cancerous or cancerous cells and tissues comprising photodynamic therapy.

The specification teaches as set forth above and cites a reference that teaches that photodynamic therapy has been applied to the treatment of skin lesions (see page 13, lines 1-3).

One cannot extrapolate the teachings of the specification to the scope of the claims because one of skill in the art cannot determine how the invention is to be specifically practiced. Moreover, one of skill in the art would not have a reasonable expectation of success in practicing the invention, absence any teaching to the contrary in the specification, because it is widely known in the art that the cytotoxic destruction of select tissues by photodynamic therapy is ineffective. For example, Nseyo, et al (*Urology* **36**: 398-402, 1990) teach:

> Present-day whole bladder photodynamic therapy (WBPDT) is cumbersome and time consuming because cystoscopic and ultrasonic manipulations are necessary to position the light emitter within the bladder. More important, WBPDT is inherently unsafe and often ineffective since neither uniform photoirradiation nor accurate light dosimetry can be achieved with the techniques employed to photoirradiate the bladder wall.

Although drawn specifically to treatment of bladder disease, the teachings of the reference cited above can be applied to any intracorporeal tissue or organ.

Also, since the claimed method of photodynamic therapy requires contacting targeted cells with a thiazine dye, there are additional problems that limit the efficacy of the method that need be addressed. For example, the refractory nature of cancer to drugs is well known in the art. Jain (*Scientific American* **271**: 58-65, 1994) teaches that most tumors resist full penetration by anticancer agents (page 58, column 1) and that scientists need to put expanded effort into uncovering the reasons why therapeutic agents that show encouraging promise in the laboratory often turn out to be ineffective

in the treatment of common solid tumors (page 65, column 3). Curti (Critical Reviews in Oncology/Hematology 14: 29-39, 1993) teaches that solid tumors resist destruction by chemotherapy agents and that although strategies to overcome defense mechanisms of neoplastic cells have been developed and tested in a number of patients, success has been limited. Curti also teaches that it is certainly possible that cancer cells possess many as yet undefined additional molecular mechanisms to defeat chemotherapy treatment strategies and, if this is true, designing effective chemotherapeutic regimens for solid tumors may prove a daunting task (paragraph bridging pages 29-30). Curti concludes that knowledge about the physical barriers to drug delivery in tumors is a work in progress (page 36, column 2). Thus, it is clear that based on the state of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the method would function effectively to selectively eradicate dysplastic, pre-cancerous, or cancerous cells from intracorporeal tissues and organs.

In addition, Hartwell, et al (*Science* **278**: 64-1068, 1997) teach that an effective chemotherapeutic must selectively kill tumor cells, that most anticancer drugs have been discovered by serendipity, and that the molecular alterations that provide selective tumor cell killing are unknown. Hartwell, et al teach that even understanding the detailed molecular mechanism by which a drug acts often provides little insight into why the treated tumor cell dies (paragraph bridging pages 1064-1065) and Jain (cited supra) specifically teaches that systemic treatment typically consists of chemotherapeutic drugs that are toxic to dividing cells (page 58, column 2). It appears that the compositions of the method are not selective for tumor cells nor would it be expected that the formulation would act only on dividing cells, since the dye or stain would be taken up by normal cells and tissues.

Furthermore, anti-tumor agents must accomplish several tasks to be effective. They must be delivered into the circulation that supplies the tumor and interact at the proper site, and they must do so at a sufficient concentration and for a sufficient period of time so as to be effective. Also, the targeted cells must not have an alternate means of survival despite action at the proper site for the drug. In addition, variables such as biological stability, half-life, and clearance from the blood are important parameters in

achieving successful therapy. The composition may be inactivated *in vivo* before producing a sufficient effect, for example, by degradation, immunological activation, or due to an inherently short half-life. The composition may not otherwise reach the target because of its inability to penetrate tissues or cells where its activity is to be exerted. Alternatively, the composition may be absorbed by fluids, cells and tissues where the formulation has no effect and circulation into the target area may be insufficient to carry the composition and to permit a large enough local concentration to be established.

Finally, Gura (*Science* **278**: 1041-1042, 1997) teaches that researchers face the problem of sifting through potential anticancer agents to find ones promising enough to make human clinical trials worthwhile (abstract). Gura teaches that since formal screening began in 1955, many thousands of drugs have shown activity in either cell or animal models, but that only 39 have actually been shown to be useful for chemotherapy (page 1041, first and second paragraphs). However, it is noted that the specification does not teach which, if any thiazine dye is efficacious in treating a cell or an animal model, let alone, a human.

The specification does not provide sufficient guidance with regard to these issues; nor does it propose or explain the rationale by which these shortcomings or misconceptions are rendered solved by the claimed invention or to be considered inaccurate. Furthermore, the specification does not teach that how the method can be applied to any particular tissue type or cell type, and to which, if any, of these tissues and cells the method cannot be applied.

Moreover, the specification provides no working examples that would provide guidance to one skilled in the art to use the invention. Accordingly, no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed method or to use the invention, commensurate in scope with the claims, with a reasonable expectation of success.

In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1, 5, 7-13, and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5, and 7-12 are vague and indefinite because claims 1 and 12 recite the phrase "comparing the reflected spectrum". Recitation of the phrase renders the claim vague and indefinite because it is not clear how the spectra are to be compared or for that matter, what aspect or characteristic of the spectrum (e.g. wavelength, intensity, etc.) are to be compared with the library of previously obtained spectra. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Claims 1, 5, and 7-12 are vague and indefinite because claims 1 and 12 recite the phrase, "with a library of previously obtained spectra". Recitation of the phrase renders the claim vague and indefinite because it cannot be determined from which tissue or cells that said library of previously obtained spectra is to be obtained prior to steps (a)-(d) and from what source said tissue and cells are to be derived. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Claims 1, 5, and 7-12 are vague and indefinite because claims 1 and 12 recite the phrase "correlating the reflected light spectrum with a disease state". Recitation of the phrase renders the claim vague and indefinite because it cannot be ascertained how the correlating the reflected light spectrum with a disease state leads to a diagnosis of a disease state in a living organism. How is the spectrum of reflected light and disease state related? Is this relationship true of every type of spectrum of reflected light generated by various and different thiazine dyes? Is the relationship true of every type of disease state? In other words, it is unclear how the method is to be used to meet the objective recited in the preamble of the claim. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Claim 12 is further rendered indefinite by the recitation of the step "correlating the reflected light spectrum". Recitation of the step renders the claim indefinite because it cannot be determined to what other quantity the reflected light spectrum is to be correlated, but for that matter, it is unclear how one could correlate the reflected light spectrum before actually measuring it. In this latter regard, it also noted that according to step (c) of the claim, the reflected light spectrum is generated, measured, and recorded simultaneously, but apparently before step (e), in which the reflected light is directed to a spectrometer to be measured. Therefore, the recitation of the claimed method is generally confusing. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Claims 13 and 17-19 are indefinite because claim 13 recites the phrase "monitoring the reflected spectrum". Recitation of the phrase renders the claim indefinite because it cannot be determined which aspect or characteristic of the spectrum is required by the claim to be monitored. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Claims 13 and 17-19 are indefinite because claim 13 does not recite a positive process step that clearly relates back to the preamble of the claim. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. Amending claim 13 to recite, for example, the phrase "whereby said dysplastic, pre-cancerous, or cancerous cells are destroyed" at the end of the last line of the claim can obviate this rejection.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5,784,162-A, as evidenced by Vaezy, et *al (Journal of Microscopy* **163**: 85-94, 1991) and Marchesini, et *al (Photochemistry and Photobiology* **55**: 515-522, 1992).

US 6,096,873-A specifically discloses a spectral bio-imaging system that consists of a measurement system and analysis software (column 2, lines 3-12). The reference teaches spectral imaging methods for *in situ* medical diagnosis and treatment comprising preparing a sample to be imaged, viewing the sample through an optical device optically connected to a spectrometer, collecting and measuring incident light using a detector, and collecting and interpreting data using a mathematical algorithm (abstract and claim 54 of the prior art).

Importantly, the reference specifically teaches that the collimated incident light may be light *reflected* by the sample (column 39, lines 56-58; see claim 5 of the prior art also).

The reference teaches that the spectral bio-imaging systems can be used to compare the spectrum of reflected light and, therefore, are useful in all applications in which subtle spectral differences exist between chemical constituents whose spatial distribution and organization within an image are of interest (column 5, lines 22-26). Furthermore, numerous examples of *in situ* analyses of cells and/or tissues to either classify and/or diagnose cellular abnormalities in said cells and/or tissues are provided in the reference (in particular, see Examples 1, 6, 7, and 8). It is noted that Example 1 teaches an *in situ* analysis of a living cellular organism, but many examples of analysis of living cells and tissues are offered (see claims 11 and 17 of the prior art also). The reference teaches the advantage of the prior art invention is that it allows comparisons to be made (see column 60, line 57 to column 61, line 1).

The reference also teaches numerous methods of mathematical correlation (columns 19-25) and in particular, discloses that the mathematical algorithm can be a similarity mapping analysis program for computing a spectral difference from a reference spectrum (column 9, lines 12-16) or from several reference spectra (column 9, lines 33-37). The reference teaches that collected data could be correlated since the mathematical algorithm can compute a ratio between intensities at two different

wavelengths (column 10, lines 39-42) or the algorithm can be a linear combination analysis (column 9, line 65 to column 10, line 27).

As a specific example of a correlative analysis of data, the reference teaches (see Example 2, columns 43, line 63 to column 44, line 4):

> The purpose of this example is to show the SpectraCube™ system combined with the methods of the present invention abilities to acquire multiplex spectroscopic information from nuclei of human erythropoietic bone marrow cells and to correlate the spectroscopic data with chromatin condensation.

The reference teaches that the prior art method can be used for spectral identification of multiple fluorophores administered to cells or a tissue (column 10, lines 49-51). The reference also discloses that a metachromatic dye, such as Azure-B, which is a thiazine dye, can be used to practice the prior art methods (see Example 2, column 43, line 10). The reference also teaches that the spectral imaging methods of the prior art invention can be used to monitor a combination of several fluorophores simultaneously, in one measurement (column 1, lines 61-63).

The reference teaches that a computer can be used to measure and memorize (i.e. store) bio-imaging data points in a database file by means of software and a microprocessor (column 60, lines 29-39). Additionally, the reference teaches, "an integral part of the present invention are also a number of mathematical algorithms that the computer software employs to interpret and display the data in a meaningful way" (column 61, lines 25-28). Although, the reference does not specifically indicate that a database, per se, is used to store the imaging data points, it is generally known in the art that software programs used to store large quantities of data points are otherwise known as databases. It is further noted that it is well known in the art that a computer comprises a microprocessor.

The reference teaches that the sample of tissue or cells to be analyzed is prepared by staining with either Romanowsky-Giemsa stain, haematoxylin-eosin stain, or May-Grunwald-Giemsa stain (see claim 59), each of which are compositions comprising thiazine dyes. It is noted that each of above staining procedures is conventional. The reference also teaches that histological samples can be analyzed

(column 5, lines 47-50) to create spectral signatures suitable for identification and classification (column 22, line 18 to column 24, line 35). The reference specifically teaches in column 38, lines 47-54 that a spectral component may "correlate well with what is called 'the purple Romanowsky-Giemsa complex' ". As set forth above, the reference anticipates the use of databases to organize and store data points acquired in analyses of tissues and cells for subsequent classification purposes to create a "library of spectra" to be used for comparisons.

The reference teaches that an objective of the prior art invention is to distinguish cancer from healthy or otherwise diseased tissue or cells (column 6, lines 27-33).

In regard to the limitations in claim 8, it is noted that it is well known in the art that spectrometers are able to measure light at a given wavelength within the claimed range of wavelengths (i.e. 200-1100 nanometers). It is further noted that this particular range of wavelengths is the so-called "scattering range" of visible light spectral energy, as evidenced by Vaezy, et al, which would be expected to comprise the reflected light spectrum. In support of the assertion that an inherent feature of the typical reflectance spectrophotometer is a capability of measuring reflected light in this range of wavelengths, see Marchesini, et al. However, it is also noted that the prior art reference specifically teaches that measurements in this range of wavelengths were made (see, for example, column 41, lines 61-63 and column 59, lines 56-63).

The limitations of claim 9 require that the measurements be made and recorded by means of a photometer and one or more light filters. It is noted that a spectrometer comprises a photometer and it is well known in the art that a spectrophotometer can comprise filters that disperse light of specific wavelengths for quantification by a photometer. However, the prior art reference specifically teaches that the imaging system can comprise filters; for example, it teaches that image lowpass filters are used in analysis (see Example 2, column 43, lines 37-40). The reference also teaches that a photometer is used to measure illumination (see Example 3, column 46, lines 65-67).

In anticipation of the limitations in claim 10 and in light of the election of species, the reference specifically teaches that the tissue can be of any type, including the skin (column 40, lines 7-10). Moreover, the reference teaches that a photosensitizing dye

can be applied topically to the skin in preparation of phototherapy (see Example 3, column 46, line 13).

Anticipating the limitations in claim 11, the prior art reference teaches that the method requires background subtraction (column 61, line 42 and claim 40). In claim 27, the reference teaches that an analysis of data acquired requires determination of the spectral difference relative to a reference spectrum. The reference teaches that "a calibration procedure in which a spectrum measured prior to sample analysis is used" is also required (column 21, line 65 to column 22, line 4).

In addition, the reference anticipates claims 13 and 17-19 by teaching that the methods can be practiced to treat skin cancer (i.e. melanoma). More specifically, the reference teaches a method for photodynamic therapy that causes the destruction of cancer cells contacted by a stain, 5-aminolevulinic acid (5-ALA), which is a highly potent photosensitizer (column 46, line 8-9). The reference teaches that 5-ALA "has been shown as highly selective both in demarcating the tumor and in its photodestruction" (column 46, lines 14-15). In claim 54, the prior art teaches, "skin imaging can be performed before, during, and after a photodynamic therapy treatment", which as was noted earlier can be performed using a thiazine dye. As set forth above, US 5,784,162 A also anticipates the additional limitations recited in the claims that depend upon claim 13.

All the limitations of the claims are met.

Conclusion

14. No claims are allowed.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 6,159,686-A is cited because the reference could be used as the basis for a rejection of the claims under either 35 USC § 102 or in view of references of record, 35 USC § 103.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Art Unit 1642

slr
November 19, 2001